scenario analysis was employed. PSA cut-off levels were varied between >3ng/ml and >4ng/ml reflecting European guidance and practice variation in Ireland. Costs and benefits were discounted at 5% per annum. **RESULTS:** Extensive probabilistic sensitivity analyses highlighted wide variation in incremental cost-effectiveness ratios (ICERs). PSA testing may be cost effective using a once-off test at age 50 or age 55 depending on the ceiling ratio incorporated. Results for the ≥3ng/ml PSA cut-off consistently dominated those for the ≥4ng/ml PSA cut-off. **CONCLUSIONS:** This analysis illustrates the value MPES methods for economic modelling of interventions. The results contribute to the ongoing accumulation of evidence on the costs and benefits of PSA testing internationally.

RESEARCH ON METHODS – Databases & Management Methods

PRM56

PRELIMINARY STEPS IN THE DEVELOPMENT OF AN ALGORITHM FOR IDENTIFYING RELAPSED CLL PATIENTS IN SECONDARY DATA

Foley KA[1], Princic N[1], Bizier R[1], Hansen LG[2], Huse DM[1]

[1]*Truven Health Analytics, Cambridge, MA, USA,* [2]*Truven Health Analytics, Northwood, NH, USA*

OBJECTIVES: Despite advances in chronic lymphocytic leukemia (CLL) treatment, roughly 25% of first and 50% of second line patients experience relapse. Relapse, however, is not well coded in claims data and is not well documented in EMR data due to under reporting of patient status, variability in terminology used to report patient status, and change in disease progression over time. The goal of this analysis was to develop an algorithm to identify relapsed patients when patient status is not clearly documented. **METHODS:** CLL patients in the MarketScan® Oncology EMR Database with recorded patient status were identified. Relapse was explored using two methods: 1) recorded patient status of relapse; 2) changes in laboratory data. For the first phase of algorithm development, both indications of relapse were compared to the date of treatment initiation. Laboratory data included lymphocytes, platelets, and hemoglobin. **RESULTS:** Of 18,334 patients with CLL, 7,865 (43%) had any patient status reported. 528 had any mention of either relapse or remission and 73 (1%) patients had a record for relapse on the same date as a CLL diagnosis and no evidence of any other cancer types. For these 73 patients, the date of new treatment initiation had no relationship with the date of the first recorded relapse. Among these same patients, declines in hemoglobin and platelets, and increases in lymphocytes preceded treatment initiation by several days. **CONCLUSIONS:** Patient status does not appear to be updated regularly and documented status may not indicate decision to treat. This preliminary work suggests that lab data provide a viable source for algorithm development as they are regularly reported in the EMR and for CLL are likely linked to decision to treat. Next steps include determining the specific rule for identifying the change in lab values that triggers treatment initiation or resumption.

PRM57

OCCURRENCE, SURVIVAL AND ANNUAL COST OF COLORECTAL-, BREAST-, PROSTATE- AND LUNG CANCER IN HUNGARY

Inotai A[1], Abonyi-Tóth Z[2], Rokszin G[2], Voko Z[1]

[1]*Syreon Research Institute, Budapest, Hungary,,* [2]*RxTarget, Szolnok, Hungary*

OBJECTIVES: Evaluating effectiveness of oncological treatments and their costs becomes more and more important with respect to the high burden of malignant diseases. The aim of this research was to estimate the occurrence, survival and health care cost of colorectal-, breast-, prostate- and lung cancer patients based on the National Health Insurance Fund (NHIF) database. **METHODS:** Survival and cost analyses were performed on the NHIF database. Inclusion criteria: at least two consecutive ICD codes between 2000 and 2012, with a minimum of 30 days difference; or those with one ICD code, followed by death within 60 days. The following ICDs were considered: C18-C20 (colorectal), C33-C34 (lung), C50 (breast), C61 (prostate). 428 860 social security numbers met our inclusion criteria. The following indicators were estimated: number of new cases, mortality, time from diagnosis to treatment, survival and annual costs related and not related to the disease. **RESULTS:** In 2011, the numbers of new cases were the following: colorectal cancer: 7299 breast cancer: 5842, prostate cancer: 3162, and lung cancer: 5499. The probability of 5-year overall survival from first diagnosis were 41.3%, 75.2%, 62.1% and 17.1%, respectively. Median time from first diagnosis to treatment initiation was less than 1 month in colorectal-, breast- and prostate cancer and less than 2 months in lung cancer. Annual cost of patient was 3166 EUR (colorectal cancer), 2585 EUR (breast cancer), 2833 EUR (prostate cancer) and 4158 EUR (lung cancer), respectively (2011 average exchange rate: 279.21 HUF/EUR). These figures indicate that annual cost of care of these malignant patients are less than half of the annual cost of kidney transplanted and haemophilia patients estimated with similar methodology. **CONCLUSIONS:** Data suggest that payer's database is suitable for estimating epidemiologic and economic indicators of malignant disorders. Payer's database analysis can support evidence-based policy-making.

PRM58

UPDATE OF THE PATIENT-REPORTED OUTCOME AND QUALITY OF LIFE INSTRUMENTS DATABASE (PROQOLID): INTEGRATION OF THE NEW COA TAXONOMY - THE CLINRO EXAMPLE

Perrier LL, Conway K, Acquadro C

Mapi Research Trust, Lyon, France

OBJECTIVES: In 2002, PROQOLID was launched to provide an overview of existing PRO instruments. In October 2011, the term Clinical Outcome Assessments (COAs) was introduced to better reflect the importance of the source of information in measurements: patients (PROs), clinicians (ClinROs), and observers (ObsROs). In May 2013, a new category was added: Performance outcome assessments (PerfOs). With this evolving taxonomy, including information about all COAs might become a crucial step in developing PROQOLID. The objective of this study was: (1) To review how ClinROs are currently reported in PROQOLID; and (2) To propose (if needed) ways of clarifying and updating ClinRO information. **METHODS:** PROQOLID was searched on April 9, 2014 to retrieve current information about ClinROs using an advanced search engine. **RESULTS:** The ClinRO information was found under the category "mode of administration" in the subcategory "clinician-rated." Out of the 801 questionnaires in the database, fifty-two (6.5%) were identified as ClinROs. Out of these 52 questionnaires, nine were generic. Eight different therapeutic areas were identified (i.e., digestive system diseases, musculoskeletal diseases, neoplasms, nervous system diseases, respiratory tract diseases, psychiatric disorders, pathological conditions signs and symptoms, and skin and connective tissue diseases), representing 17 different indications, and 33.33% of the therapeutic areas included in PROQOLID (n=24). The most represented therapeutic area was psychiatry (n=23) followed by nervous diseases (n=7). Only two questionnaires were specific to children: the Pediatric Evaluation of Disabilty Inventory and the WeeFIM®. To better individualize ClinRO information in PROQOLID, it is proposed to create a new meta-category, i.e., type of COA (PRO, ClinRO, ObsRO and PerfRO). It is also recommended to expand PROQOLID to all COAs. **CONCLUSIONS:** This review has shown that PROQOLID already includes ClinRO information. Recommendations are given on how to modify the organization and content of the database to present information on all COAs.

PRM59

ECOA LICENSING: LESSONS LEARNED FROM THE COPYRIGHT OF COA TRANSLATIONS AND SPECIFICITIES OF ECOAS

Anfray C[1], Conway K[2], Acquadro C[2]

[1]*Mapi, Lyon, France,* [2]*Mapi Research Trust, Lyon, France*

OBJECTIVES: Electronic Clinical Outcome Assessments (eCOAs) are increasingly being used in clinical trials and their use is encouraged by regulatory authorities. Licensing is a key issue for their appropriate utilization. The objective of this abstract is to make recommendations about eCOA licensing using lessons learned from the COA translation licensing. **METHODS:** Publications about licensing of COA translations were searched and a review of the eCOAs specificities was performed using information available from e-vendors. **RESULTS:** Very few publications exist about the licensing of COA translations. The ISOQOL TCA SIG has developed a draft reflection paper which considers that translations are derivative work of original questionnaires. As such, they recommend that the copyright of a COA and its translations should be owned by a unique entity, generally the original developer to harmonize and facilitate conditions of access and use. They state that distribution should be centralized to facilitate access to questionnaires, maintain reliable information about them, and control their use. Review of the e-vendors information shows that eCOAs are often customized, with proprietary devices and softwares, and cannot be shared across users. As a consequence, there is a multiplication of e-versions for a same content. Equivalence between paper and e-versions and between e-versions is then a major concern. The review also shows that migration from paper to the electronic platform/device implies changes to the content and format of the paper version. Therefore the eCOAs can be considered as derivative works of an original COA and lessons learned from copyright of translations may apply. Examples will be provided. **CONCLUSIONS:** Centralized copyright ownership by the owner of the original COA and centralized licensing process for eCOAs should be discussed with all stakeholders to help controlling use and users and to protect the integrity of the instrument across e-versions by providing clear rules of e-implementation.

PRM60

MAPPING EUROPEAN DATABASE USAGE: AN ANALYSIS OF PUBLISHED DATA TYPES

Langham S[1], Pooley N[2], Weir S[1]

[1]*PHMR Associates, London, UK,* [2]*PHMR Associates, Newcastle upon Tyne, UK*

OBJECTIVES: To determine how European databases are used to support pharmacoepidemiological research. Randomised, controlled trials remain the gold standard for evaluation of drug efficacy and safety. However, the only way of identifying treatment pathways and improving understanding of real world costs and outcomes at different stages of care is via longitudinal observational studies. Observational data from electronic health records (EHRs) are essential to this pharmaco-epidemiological research. Different European databases have different strengths in terms of data types and availability. Identifying these strengths will help to select the right database for a particular study. In this context, one approach to increasing our understanding is to analyse types of published data to determine how databases have historically been used to support research. **METHODS:** We identified peer-reviewed publications over the last 10 years from one popular longitudinal general practice patient database with some secondary care links. The publications were assigned to disease areas and study types (e.g. prevalence, resource utilisation, treatment patterns, outcomes etc). **RESULTS:** Based on this mapping exercise, we identified the types of studies and the disease areas that this European database commonly supports. We also highlight gaps in disease area coverage and types of real world evidence studies and discuss potential reasons for this underuse. **CONCLUSIONS:** European observational data from EHRs provide increasingly important information for stakeholders of new treatment, however there are still a number of gaps in terms of disease areas and study types that these databases can support.

PRM61

USING AN INNOVATIVE APPROACH TO BUILD A PROSPECTIVE DIABETES COHORT REGISTRY OF PATIENTS WITH TYPE 2 DIABETES IN GERMANY: DIAREG

Garcia Alvarez L[1], Rathmann W[2], Bode-Greuel K[3], Engelhard J[3], Bush S[4], Schröder-Bernhardi D[3], Hiller J[1]

[1]*IMS Health, London, UK,* [2]*German Diabetes Center, Duesseldorf, Germany,* [3]*IMS Health, Frankfurt am Main, Germany,* [4]*AstraZeneca, Hamburg Area, Germany*

OBJECTIVES: The lack of accessible, comprehensive sources of medical and quality of life data in Germany has partially hindered the ability to research diabetes clinical practice. The aim of this study was to build a prospective, national, multi-centre Type 2 diabetes mellitus (T2DM) registry using an innovative data collection methodology to better understand the disease specific epidemiology, treatment patterns and